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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|------------------------|---------------------|------------------|
| 10/711,695                       | 09/30/2004  | Jean- Francois Durette | 10328-1-P9          | 5694             |
| 23486                            | 7590        | 03/18/2008             | EXAMINER            |                  |
| SHUTTLEWORTH & INGERSOLL, P.L.C. |             |                        | MATTHEWS, WILLIAM H |                  |
| 115 3RD STREET SE, SUITE 500     |             |                        | ART UNIT            | PAPER NUMBER     |
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|                                  |             |                        | 03/18/2008          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |   |                         |
|------------------------------|---|-------------------------|
| <b>Office Action Summary</b> | Application No.                         | Applicant(s)            |
|                              | 10/711,695                              | DURETTE, JEAN- FRANCOIS |
|                              | Examiner<br>William H. Matthews (Howie) | Art Unit<br>3774        |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 May 2005.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 and 12-29 is/are rejected.
- 7) Claim(s) 11 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-30-04, 5-27-05</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,12-17,19 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen USPN 3070808.

Allen disclose in figures 1-4 an orbital implant formed of one-piece acrylic and having a quasi-spherical shape and astigmatic features as claimed (see figures 2-3). The plurality of tunnels/chimneys (as broadly claimed) are described at c3:28-55. Valleys, mounds, and a visible marking are shown in figure 1.

Claims 20,26,27,29 are rejected under 35 U.S.C. 102(b) as being anticipated by Finger USPN 6419698.

Finger disclose in figures 5-6 an orbital implant comprising 2 pieces combined being implantation (c3:26-30). They may comprise silicone or acrylic (c3:64-65) and have a quasi-spherical shape defined by an elongation on one side (see figure 5).

Claims 20-23, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hicks et al. USPN 6346121.

Hicks et al. disclose acrylic orbital implants comprising two pieces joined together and having tunnels and chimneys capable of tissue ingrowth and passage of sutures. See figures 2,5, c3:57-c5:4, and Examples 1,3, and 5.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8,18, and 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen 3070808, as applied above, and in further view of Kelman USPN 4370760 and/or Hicks et al. USPN 6346121.

Allen meet the limitations of claims 7-8,18, and 20-29 as described above but lack the express written disclosure of using two separate parts or joining two parts by ultrasonic welding. Each of Kelman and Hicks teach ocular implants which may comprise unitary construction or separately constructed parts joined together. Kelman further teach the well-known use of ultrasonic welding. See Hicks c3:61-67 and Kelman c5:45-52. Furthermore, modifying a component into separately formed parts to be subsequently joined has been held to be within the realm of obvious design choice (*In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348,349 (CCPA 1961)). Also see MPEP 2144.04(V)(C). Still further, Hicks provide motivation to separate the parts in order to provide different properties along the device, and one of ordinary skill in the art would further realize a possible improvement in the manufacturing process in order to create the uniquely shaped structure of Allen including tunnels and chimneys.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the orbital implant disclosed by Allen by forming the device into separate parts, as taught by Kelman and/or Hicks, in order to provide different properties along the length of the device or to improve the manufacturing process, And further to join the parts by ultrasonic welding, as taught by Kelman, in order to securely join the parts.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen 3070808, as applied above, and in further view of Finger 6419698.

Allen meet the limitations of claim 9-10 as described above but lack the express written disclosure of using silicone. Allen does disclose that other materials well known in the art may be used (c3:3-14). Finger teaches orbital implant devices are commonly made from silicone (c1:14-24).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the orbital implant disclosed by Allen to include silicone as taught by Finger in order to provide a known biocompatible material.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Finger 6419698 in view of Kelman USPN 4370760.

Finger meet the limitations of claim 28 as described above but lack the express written disclosure of using ultrasonic welding to attach the parts. Finger does disclose that adhesives may be used. Kelman teach ocular implant devices comprising multiple

parts wherein they may be connected by adhesives or ultrasonic welding (c5:45-52) in order to securely fasten the parts.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the orbital implant disclosed by Finger to include ultrasonic welding as taught by Kelman in order to securely fasten the parts.

***Allowable Subject Matter***

Claim 11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fail to disclose nor substantially render obvious the orbital implant recited in claim 1 in combination with the anterior portion comprising two tentacles having enlarged portions and the posterior portion having holes for connecting the anterior and posterior portions.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/  
Primary Examiner  
Art Unit 3774